Decision Memo for Prostate Specific Antigen (Inclusion of ICD-9-CM Code 600.01 for BPH with Urine Obstruction) (CAG-00232N)

Decision Summary

CMS has determined that ICD-9-CM code 600.01, benign prostate hypertrophy, flows from the existing narrative for conditions for which prostate specific antigen (PSA) is reasonable and necessary. We intend to modify the NCD for PSA testingto include this code in the list of “ICD-9-CM Codes Covered by Medicare” for this service.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to the one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO:	Administrative File: CAG-00201N Prostate Specific Antigen (Inclusion of ICD-9-CM Code 600.01 for BPH with Urinary Obstruction)
FROM:	Steve Phurrough, MD, MPA Director, Coverage and Analysis Group Jesse Polansky, MD, MPH Director, Division of Items and Devices Jackie Sheridan-Moore Technical Advisor, Division of Items and Devices
RE:	Coding Analyses for Prostate Specific Antigen Testing
DATE:	June 18, 2004

I. Decision

CMS has determined that ICD-9-CM code 600.01, benign prostate hypertrophy, flows from the existing narrative for conditions for which prostate specific antigen (PSA) is reasonable and necessary. We intend to modify the NCD for PSA testing to include this code in the list of "ICD-9-CM Codes Covered by Medicare" for this service.

II. Background

On March 19, 2004 CMS began a coding analyses for expansion of ICD-9-CM codes for the prostate specific antigen NCD.Prostate specific antigen is a tumor marker for adenocarcinoma of the prostate and can predict residual tumor in the post-operative phase of prostate cancer.Also, PSA when used in conjunction with other prostate cancer tests, such as digital rectal examination, may assist in the decision making process for diagnosing prostate cancer.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. One of these NCDs was for prostate specific antigen tests. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that coverage of specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM codes covered by Medicare,” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes that do not Support Medical Necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the PSA test NCD that any ICD-9-CM code not listed in either of the ICD-9-CM covered or not covered sections would be categorized into this group that does not support medical necessity.

IV. Timeline of Recent Activities

As mentioned above, on March 10, 2000, CMS published a Notice of Proposed Rulemaking (NRPM) in the Federal Register (65 FR 13082). As an addendum to this NPRM, we proposed the 23 NCDs as negotiated by the rulemaking committee for public comment. On November 23, 2001, we published a final rule for coverage and administrative policies for clinical diagnostic laboratory services (66 FR 58788). The PSA test NCD included the ICD-9-CM codes 599.6 for urinary obstruction in the list of ICD-9-CM codes covered by Medicare.

On March 3, 2004, we received a formal request from Marcie Yoh at The Good Samaritan Hospital regarding new ICD-9 -CM codes effective October 1, 2003. Ms. Yoh noted effective October 1, 2003, ICD-9-CM added a new code 600.01 for benign prostate hypertrophy (BPD) with urinary obstruction. She stated that it is no longer valid to code BPH and urinary obstruction separately. Thus, she believed the new code 600.01 flowed from the narrative indications for PSA and should be added to the list of ICD-9-CM codes covered for that service.

On March 19, 2004 we announced in a tracking sheet posted on the Medicare coverage Internet site

(http://cms.hhs.gov/ncdr/trackingsheet.asp?id=107) that we were considering adding the code 600.01 for BPH with urinary obstruction to the list of covered codes for PSA tests and solicited public comments during a 30-day period. At the end of the public comment period, April 19, 2004, we had not received any comments.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in a proposed notice dated December 24, 2003 (68 FR 74607).

VI. CMS Analysis

As noted above, we have taken the position that the "ICD-9-CM Codes Covered by Medicare" list is intended to contain only those codes that flow from the narrative of the indication in the NCD. The PSA test NCD lists the following as an indication for testing:

“PSA is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs and symptoms (e.g., hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia and incontinence) as well as with patients with palpably abnormal prostate glands on physician exam, and in patients with other laboratory or imaging studies that suggest the possibility of a malignant prostate disorder.”

We believe that the ICD-9-CM code for benign prostate hypertrophy with urinary obstruction (600.01) flows from the existing narrative indications statement that includes lower urinary tract signs and symptoms. Consequently, we intend to issue a recurring update to the edit module implementing the NCDs to add ICD-9-CM code 600.01 to the list of the ICD-9-CM codes covered for prostate specific antigen tests.

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